

REMARKS/ARGUMENTS

This is a reply to the Office Action dated January 31, 2006.

Claims 1-12 remain in this application. No claim has been amended. Claims 13-20, which were claims previously withdrawn as directed to a non-elected invention, have now been cancelled.

Applicants acknowledge the courtesy of the interview granted to Applicant's undersigned representative on April 18, 2006. Although no specific agreement regarding patentability of any claims was reached at the conclusion of the interview, Applicants have heeded the Examiner's suggestion to submit their technical and legal remarks and clarifications presented at the interview in the form of this written response to facilitate the Examiner's further review and reconsideration of this matter. Also, a Rule 132 Declaration of the first named inventor of the instant application also is being submitted concurrently herewith which addresses the comparative evidence issues raised and discussed at the interview. The substance of the interview is summarized and incorporated into the reply provided below to the grounds of rejection set forth in the Office Action, and reference is made thereto.

Claims 1-10 have been rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Jennings (US Pat. No. 5,206,050) or Ishizuka et al. (US Pat. No. 4,579,749) taken together with Goodnight, Jr. et al. (US Pat. No. 4,091,120, "Goodnight").

The Office Action is understood to indicate that Jennings and Ishizuka et al. disclose meat analogs containing soy protein but not deflavored soy protein. Goodnight is understood to be relied upon in the Office Action as describing a treated soy protein that one of ordinary skill in the art would have found obvious to use as the soy protein used in the meat analogs of the primary references because of the "improved functionality and nutritional qualities of the treated soy protein."

As discussed at the interview conducted April 18, 2006, Applicants' reply is that the deflavored soy protein products made by the recited processing in the present invention would necessarily result in and provide a protein product source that is distinct and different than that set forth in Goodnight as the processing differences therebetween can be and have been demonstrated to result in different products.

In particular, Applicants presented their position at the interview that the "Inventive Process" and "Comparative Process 1" experimental runs of Example 14 of their own published U.S. Pat. Application No. US 2004/0161525 A1 ([0079]-[0080]) [hereafter, "the '525 publication"] do in fact provide appropriate comparative testing data showing the distinct and improved character of the deflavored soy components of products of the present invention as compared to deflavored soy made according to Example 1 of Goodnight.

To the extent the deflavored soy protein product made by processing of the invention is distinct and different from that of Goodnight, Applicants further submit that food products such as meat and meat analogs incorporating it also will differ from one another.

In particular, Applicants submit that Comparative Process 1 of Example 14 of their '525 publication is a sufficiently close and reasonable representation of Example 1 of Goodnight in view of the following reasons. Therefore, comparative testing data is available and made of record in this application demonstrating that the soy products made by processing according to the present invention are distinct and different from that resulting from Goodnight's processing approach.

Initially, Applicants clarify that although Comparative Process 1 of Example 14 of their '525 publication ([0080]) parenthetically states "Based on U.S. Pat. No. 4,420,425 [to Lawhon]", that this was merely intended to mean that the comparison sample was broadly based on Lawhon's Example 1 insofar as some operational parameters, but not all. Comparative Process 1 of their '525 publication was not implemented as an exact one-to-one duplication thereof, as is apparent by comparison of the actual test protocols and parameters used in and described for Comparative Process 1 and Example 1 of Lawhon. Thus, Lawhon's Example 1 is not relevant to these discussions (e.g., its UF molecular weight cutoff of 100,000 daltons and temperature condition of 61-69°C were not used in said Comparative Process 1 of the '525 publication). Thus, the "Based on ..." heading Comparative Process 1 does not indicate and should not be construed as meaning that the comparison example of the '525 publication was not relevant to other prior art as well, such as Goodnight.

Referencing the comparison chart presented and discussed at the interview, which is reproduced below, to the extent there are some seeming discrepancies between some of the processing parameters used in Comparative Process 1 of Example 14 the '525 publication and Example 1 of Goodnight, Applicants submit that these differences are not significant and would not be expected by one of ordinary skill to significantly affect the ultimate product that is obtained for the reasons explained after the following chart and in the accompanying Rule 132 declaration.

| | 10/696,603 (dkt. 77024) | Assignee's/Inventors' US 2004/0161525 A1 | | US 4091120 (Goodnight) |
|-------------------------|---|--|--|------------------------|
| Process Variable | Example 11 | Example 14- "Inventive Process" | Example 14- "Comparative Process 1" | Example 1 |
| Soy starting material | Soy flour | Soy flour | Soy flour | Soy flakes |
| Soy/water ratio | 30/270 (11%) | 30/270 (11%) | 30/270 (11%) | 50/800 (6%) |
| Solubilization pH | 10 | 10.0 | 9.0 | 7.2 |
| UF temp. | - | 50°C | 50°C | 45°C |
| UF molecular wt. cutoff | 10,000 | 10,000 | 30,000 | 5,000 |
| UF pH, begin/end | 10/10 | 10.0/10.0 | 7.5/7.0 | 7.36/7.22 |
| | De-flavored Soy Product Properties | Example 14- "Inventive Process" | Example 14- "Comparative Process 1" | |
| | Flavor profile | "best overall flavor profile" compared to Comp. Pro. 1 | | |
| | Particle size, μm | 20.2 | 115.7 | |
| | % solubility | 62.4 | 59.9 | |
| | Water retention, g water/g protein | 6.1 | 3.8 | |
| | Particle microstructure | Thin walls | Thin and thick walls | |

Soy starting material: The difference in soy flour from soy flakes as the form of the soy starting material is not critical as the solubilization treatment will act on either soy flour or soy flakes in generally the same manner. Goodnight does not differentiate between soy flour or soy flakes (col. 2, lines 32-34). After solubilization, and prior to ultrafiltration, the spent flakes or flour are centrifuged or filtered out and are not present in the ultimate product of either Example 1 of Goodnight (col. lines 8-15) or the Inventive Process and Comparative Process 1 of Example 14 of the '525 publication.

Soy/water ratio: the water proportion does not play a major factor in the end product. Instead, the proportion of water used to soy has more to do with practical considerations as the amount of water effects the time through filter and product drying time. Use of higher proportions of water will increase the time period needed to complete the ultrafiltration. Lower proportions of water will increase product yield rate and improve economics of the operation but if the soy content becomes too high then the viscosity will also becomes too high such that it can become a productivity limiting factor as the filter can foul and filtration can slow.

Solubilization pH: Example 1 of Goodnight describes a pH of 7.2 but it teaches a broader preferred range of 7-9 (col. 2, lines 63-64), which overlaps with the pH used in Comparative Process 1 of Example 14. Also, as explained in the present application (e.g., page 11, lines 3-14), the use of a higher pH of 9, such as in Comparative Process 1 of the '525 publication, would tend to improve deflavoring results, if anything, such that

Comparative Process 1 provides a closer and more than fair comparison to the present invention than Goodnight insofar as this parameter.

UF temperature: Comparative Process 1 of Example 14 describes "about 50°C" (col. which approximates the 45°C UF temp. used in Example 1 of Goodnight.

UF molecular weight cutoff: The numerical difference in the molecular weight cutoff as between 30,000 used in Comparative Process 1 of the '525 publication and 5,000 in Example 1 of Goodnight would not be technically expected to result in different products therebetween. As explained in the present application, the UF membrane must be able to pass the undesirable flavoring compounds having molecular weights lower than 1,000 (page 10, lines 3-7). The molecular weight cutoff is expressed as being preferably 1,000 to 50,000, more preferably 10,000-30,000 in the present application (page 10, lines 7-9). As can be appreciated, as higher cutoff values are used than 1,000 daltons the undesirable compounds will continue to pass through the membrane but larger proportions of protein product also will pass through the membrane with it, reducing product yield amounts (e.g., see page 20, lines 21-22). Goodnight also suggests an appreciation of these qualitative considerations at the lower limit and practical considerations at the upper limit in referring a minimum molecular weight in the range of about 10,000 to 50,000 for the semi-permeable membrane used for ultrafiltration (col. 3, lines 51-54).

UF pH begin/end: the begin/end UF pH values for Comparative Process 1 of the '525 publication compare well to those of Example 1 of Goodnight. In contrast, Inventive Process 1 maintained the pH at 10.0 during ultrafiltration.

In view of at least the above technical clarifications, Applicants submit that Comparative Process 1 of Example 14 of their '525 publication is a fair and sufficiently close representation of Example 1 of Goodnight in all important respects.

Deflavored Soy Product Properties: As seen in the flavor profile, particle size, water retention and particle microstructure properties reported in Example 14 of the '525 publication for the soy products of Inventive Process 1 and Comparative Process 1, the processing of the invention resulted in soy products that are distinct and superior to those manufactured according to a comparative process representative of Example 1 of Goodnight. As explained in the '525 publication, these distinct and superior properties favorably impact appearance, mouthfeel, and so forth, in food products containing the soy protein material manufactured according to the present invention.

These results are surprising and would not have been expected from Goodnight's teachings or other prior art of record.

Applicants submit that this factual evidence, which is currently publicly known through its publication, and also was so at the time of the final rejection, is adequate to rebut and overcome any *prima facie* case of obviousness arguably presented by the combination of references including Goodnight.

Furthermore, as indicated above, Applicants are concurrently filing the Rule 132 Declaration of Ahmad Akashe as additional evidence on the commensurateness of the comparison studies conducted in Example 14 of the '525 publication between a product representative of the present invention and another representative of Goodnight, and also the provided showings in said Example 14 of the non-obvious differences found between the soy materials of Goodnight and those of the presently claimed invention. Reference is made thereto.

In view of the above, Applicants respectfully submit that the combination of Jennings or Ishizuka et al. and Goodnight does not defeat the patentability of the present invention, and, accordingly, they request reconsideration and withdrawal of this rejection.

Claims 1-10 also have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over claims 22-23 of copending appln. No. 11/209105 or claims 24-30 of copending appln. No. 10/697402 in view of Goodnight and either Jennings or Ishikawa et al. Claims 11-12 also have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting over the above combination in further view of Hayhurst et al. and Komatsu et al.

Applicants submit that these grounds of rejection are inapplicable for the same reasons discussed above insofar as the comparative testing of record which distinguishes the Goodnight reference.

In view of the above, it is believed that this application is in condition for allowance, and notice of such is respectfully requested.

Respectfully submitted,

FITCH, EVEN, TABIN & FLANNERY

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